ORICARE

DEC 1 8 2012

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510(k) Summary

K122875

Date Prepared: September 11, 2012

Applicant:
Oricare, Inc.
1900 AM Drive
Quakertown, Pa 18951
Registration Number: 3009129579

Contact Person:
Fred Cowdery
QA/RA Manager
Ph 267-347-4544
Fax 215-538-2578

Device Trade/Proprietary Name: L2700 Series OR Surgical Luminaires

Device Name: Common / Usual: Light, Surgical, Ceiling Mounted

Classification Name: Surgical Lamp (21 CFR 878.4580, Product Code: FSY)

Predicate Devices:
Maquet PowerLED Surgical Lighting System (K070442)
Steris Harmony LED-1 Surgical Lighting System (K072072)

Device Description / Technological Characteristics

OL 2700 series Surgical Lamps are ceiling mounted Surgical Lamps, suitable for providing supplemental illumination, with reduced shadowing effects during surgical and non-surgical procedures.
The lighting system utilizes LED's for illumination and is powered from a standard 115VAC voltage source. The head design is comprised of multiple LED's (Light Emitting Diodes). It provides a cool, color corrected light which is adjustable with 10 levels of intensity. The light path design provides an extended light depth so that the beam requires no manual focus. Light generated by the LEDs is focused by optical lens to achieve an ideal irradiance pattern.

The OL 2700 series LED surgical light can be configured with one or two light heads, the primary light head is useful for major illumination while the secondary light head is for ancillary illumination. The lights can also provide low level background lighting for endoscopic surgery.

Oricare L2700 series Operating Room Lamps can be easily used in conjunction with the optional SD or HD video systems, to document surgical procedures for training purposes, make use of live transmissions or consult with external surgeons during operations. The camera system is available in different versions and can be used with integrated OR systems. It delivers images in SD or HD quality straight to the TFT monitor.

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Table 1 below defines the available configurations of the L2700 Series Surgical Lamps.

Table 1

Oricare Part Number	Model Number / Description
LA5003	L2770 Operating Room Lamp
LA5004	L2750 Operating Room Lamp
LA5005	L2770L2750 Operating Room Lamp
LA5006	L2770L2770 Operating Room Lamp
LA5007	L2750L2750 Operating Room Lamp
LA5012	L27702750 OR Lamp with SD Video and Display
LA5013	L27702750 OR Lamp with HD Video and Display

Intended Use:

The Oricare L2700 Series Surgical Lamps provide illumination at varying illumination levels to the patient surgical area and provide video-visual procedural support for medical staff during surgical procedures.

Performance Testing:

Comprehensive performance testing has been conducted on the L2700 Series Surgical Luminaires in accordance with various recognized industry standards by a recognized third party organization. Product compliance with the following standards included: IEC 60601-1:2005 3rd edition, IEC 60601-1-2:2007, IEC 60601-2-41:2009, ISO 14971:2009, IEC 60601-1-6.

Software was evaluated in accordance with relevant FDA Software Guidance Document, per the requirements assigned for software classified as a "Minor Level of Concern".

The combined testing and analysis of results provides assurance that the device meets the requirements for safety and essential performance and is effective for its intended use.

Non-clinical Comparisons to Predicate Device:

The differences between the proposed and predicate devices are limited to differences in design, material, and operational. These differences do not raise any new issues of safety and efficacy.

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Substantial Equivalence:

The Oricare L2700 Surgical Luminaires are believed to be substantially equivalent to currently marketed Surgical Lamps with regards to intended use, safety and effectiveness, technology, and performance.

Similar to the predicate devices, the L2700 Surgical Luminaires provide a shadowless light source using LEDs as the main light source. The L2700 Surgical Luminaires provide a variable intensity light source designed to provide visible illumination of the surgical field and the patient and to provide video-visual procedural support for the hospital staff during surgical procedures.

Conclusions:

Based upon the information provided herein this 510(k) Premarket Notification, we conclude that the L2700 Series Surgical Luminaires are substantially equivalent to the identified predicate devices and are safe and effective when used as intended.

Fred Cowdery
Manager, Regulatory Affairs and Quality Assurance
Oricare, Inc.
1900 AM Drive
Quakertown, PA. 18951

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 18, 2012

Oricare, Inc.
% Mr. Fred Cowdery
QA/RA Manager
1900 AM Drive
Quakertown, Pennsylvania 18951

Re: K122875
Trade/Device Name: L2700 Series OR Surgical Luminaires
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: September 12, 2012
Received: September 19, 2012

Dear Mr. Cowdery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510 (k) Number (if known) K122875

Device Name: Oricare L2700 Series Surgical Lamp

Indications for Use:

The Oricare L2700 Series Surgical Lamps provide illumination at varying illumination levels to the patient surgical area and provide video-visual procedural support for medical staff during surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off)

Division of Surgical Devices

510(k) Number K122875